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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/092,210

03/06/2002

Iwao Katsuyama

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05/05/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,210

Applicant(s)

KATSUYAMA, IWAQ

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/10/2006; 10/4/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2005 has been entered.
2. Claims 19-38 are pending.
3. Applicant's election with traverse of claims 24-38 in the reply filed on February 10, 2006 is acknowledged. The traversal is on the ground(s) that there is no undue administrative burden placed upon the Examiner to search and consider all the claims. This is not found persuasive because as articulated in the Requirement, each set of claims is classified in different U.S. Patent Classification. Different classification of claims is *prima facie* evidence that the search for each set of claims is not coextensive, and imposes undue administrative search burden. See MPEP § 803. Thus, the requirement is still deemed proper and is therefore made FINAL.
4. Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 10, 2006.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 24-29, 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al US Patent 5,142,647 in view of JP 07-133225 ("JP '225").

The instant claims are directed to methods for evaluating the action of a drug against ciliary muscles for evaluating the effect of the drug against asthenopia comprising the steps of inducing contraction of ciliary muscles and contacting ciliary muscles with a medicine and assessing the decrease in ciliary muscle tension.

Nakagawa teaches an in vitro method of measuring effects of pharmaceutical solutions against biological specimen including smooth muscles and the like (see abstract; col 2, line 46-col 3, line 25). The Magnus Apparatus of Nakagawa contains a chamber wherein a muscle specimen is immersed into a solution from one end and is attached to a transducer from the other end for detection of the tensile force of the specimen (see figure 1, numeral 1-5, 10; col 5, line 60-col 6, line 14; col 6, lines 40-67). The chamber also known as magnus tube can contain a solution of tensile stimulant or the pharmaceutical agent of choice to be tested. (see figure 1, col 3, line 50-col 4, line 67). Nakagawa fails to explicitly employ ciliary muscles in his magnus apparatus or assess the activity of drugs against asthenopia.

JP '225 describes methods of performing a pharmacological test to assess the effects of a drug on ciliary muscle contraction for treatment of asthenopia. (Abstract). The methods of JP '225 teaches all elemental steps of the instant claims. The method in JP '225 comprise extracting the ciliary muscles of a cow eyeball which meets the instant step of enucleating ciliary muscles of a non-human mammal. (see para 0022-0023). The method of JP '225 also comprises hanging the ciliary muscle and placing it in a Magnus apparatus (tubing) and applying a compound of interest (compound A) to the hung muscle and then determining the contraction strength of the ciliary muscles.

Art Unit: 1617

(see para 0023). The ciliary muscles in JP '225 are first contracted or pretreated with compound A to induce astopia. This step in JP '225 meets the limitation of inducing contraction of ciliary muscles. The step of adding KCl in JP '225 meets the instant step of contacting a "medicine" to the contracted muscles. JP '225 describes that the rate of decrease in tension was about 22.9% which meets the limitations of the instant claims. Examiner points out in the process claims, the intended use does not impart patentability over the prior art absent a manipulative difference. Thus, all process steps of the instant claims are met.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to assess the activity of suitable drugs such as Compound A in JP '225 against other chemical stimulants in the Magnus Apparatus of Nakagawa, because as suggested by both Nakagawa and JP'225, such device and process steps provide in vitro assessment of the efficacy of drugs on contracted ciliary muscles.

Further, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the tension degree of muscle tension to best mimic the in vivo tension of asthopic ciliary muscles.

such as acetylcholine, as described by Kitagawa, or direct electrical stimulation, as described by Yoshikawa.

One of ordinary skill in the art would have had a reasonable expectation of success in achieving meaningful clinical data by predicting the degree of contraction of ciliary muscles against other known stimulants. Further, assessing the degree of

Art Unit: 1617

contraction decrease is a function of the doses of an agonist or antagonist drug employed and is achieved by routine experimentation.

6. Claims 30-31, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al US Patent 5,142,647 in view of JP 07-133225 ("JP '225") as applied to claims 24-29, 32-36 and further in view of JP '225 in view of Kitagaw (Japanese Journal of Pharmacology, 1989, Vol 49, suppl. pp. 281) .

The teachings of Nakagawa and JP '225 are described above. Their combined teachings fails to employ acetylcholine as the stimulatory agent for contracting ciliary muscles prior to their exposure to the drug of interest for asthenopia.

Kitagaw teaches acetylcholine-induced contraction of smooth muscles and measuring the degree of contraction by automated and manual Magnus apparatus.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to further use chemical stimulatanst such as acetylcholine and assess the activity of Compound A in JP '225 against other chemical stimulants.

One of ordinary skill in the art would have had a reasonable expectation of success in achieving meaningful clinical data by predicting the degree of contraction of ciliary muscles against other known stimulants. Further, assessing the degree of contraction decrease is a function of the doses of an agonist or antagonist drug employed and is achieved by routine experimentation.

Conclusion

No claims are allowed.

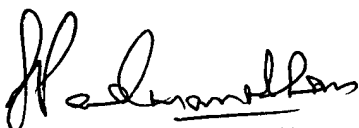
Art Unit: 1617

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER